



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 30, 2009

MEMORANDUM

SUBJECT: Secondary Review of AHETF Field Studies: AHE17 - 21

PC Code: 080807, 081901	DP Barcode: 343367
MRID No.: 47212805-47212809	Registration No.: N/A
PRIA II Category: NA	Regulatory Action: Secondary Review
Risk Assessment Type: N/A	simazine (CAS 122-34-9)
TXR No.: N/A	chlorothalonil (CAS 1897-45-6)

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This memorandum provides secondary review comments on five field studies performed by the Agricultural Handlers Exposure Task Force (AHETF). Each field study (AHE17 – AHE21) consists of dermal and inhalation exposure measurements of five subjects performing open mixing/loading of dry flowable formulations. In some of the studies, various applicator scenarios were also monitored based on logistical convenience coupled with specific scenario criteria established by AHETF to populate other Handlers Scenarios (e.g., ground boom application with open cab tractors) in the AHETF database. The studies addressed in this memorandum are as follows:

- AHE17: Determination of Dermal and Inhalation Exposure to Workers in Southern Illinois, Open Pour Mixing/Loading a Dry Flowable Pesticide Product and During application to Various Sites by a Variety of Application Methods [MRID 47212805]. Surrogate chemical: simazine
- AHE18: Determination of Dermal and Inhalation Exposure to Workers in the Pacific Northwest During Open Pour Mixing/Loading a Dry Flowable Pesticide Product and During Application to Various Sites by a Variety of Application Methods [MRID 47212806]. Surrogate chemical: chlorothalonil
- AHE19: Determination of Dermal and Inhalation Exposure to Workers in Eastern Illinois During Open Pour Mixing/Loading a Dry Flowable Pesticide Product [MRID 47212807]. Surrogate chemical: simazine
- AHE20: Determination of Dermal and Inhalation Exposure to Workers in Southern Georgia During Open Pour Mixing/Loading a Dry Flowable Pesticide Product and During Application to Various Sites by a Variety of Application Methods [MRID 47212808]. Surrogate chemical: chlorothalonil
- AHE21: Determination of Dermal and Inhalation Exposure to Workers in Northern Florida During Open Pour Mixing/Loading a Dry Flowable Pesticide Product and During Application to Various Sites by a Variety of Application Methods [MRID 47212809]. Surrogate chemical: chlorothalonil

Background

The 25 subjects performing dry flowable (DF) mixing/loading activities in these field studies are referred to as monitoring units (MU) and will be used by the AHETF to populate the AHETF Dry Flowable Mixer/Loader Scenario. Each field study has five mixing/loading MUs and is referred to as a cluster. Each cluster is meant to be representative of potential regional distinctions that can influence handler exposure. Within each cluster, the subjects participating in the study apply different amounts of active ingredient (ai). The ai strata for the DF scenario are as follows: 5-25, 50-70, 150-240, 500-700 and 1,500-2,000 pounds ai. This stratification of ai handled and regional clustering scheme has been designed by the AHETF to set scenario specific benchmarks in which the calculated geometric mean, arithmetic mean and the 95th percentile of the distribution that are within K-fold, of the true parameter 95% of the time. A "K" value of 3 was selected here as the goal and sample size/cluster configuration was selected here with this target in mind. A secondary goal of the AHETF is that the data achieve a minimum of 80 percent statistical power to distinguish between complete proportionality and complete independence with respect to the amount of ai handled and exposure.

A monograph of the Dry Flowable Scenario is presented in a separate AHETF report entitled Agricultural Handler Exposure Scenario Monograph: Mixing and Loading Dry

Flowable Formulations (AHE1001, MRID 47259801). The purpose of this memorandum is to present secondary review comments on the technical aspects of the five individual field studies. Primary reviews of AHETF 17 – 21 have been performed by Versar and provided to the AHETF. A formal review of the Dry Flowable scenario monograph will be conducted following discussions with the AHETF, the California Department of Pesticide Regulation (DPR) and Canada's Pest Management Regulatory Agency (PMRA). These discussions will likely focus on the recommendations made in this document such as adjusting the hand rinse samples collected in the five field studies addressed in this review.

The studies used to populate AHETF's mixer/loader, dry flowable scenario are based on a wide variety of mixing/loading conditions in four, possibly five, distinct geographic regions (two study sites were located in central Illinois). In study AHE17, one individual was measured twice. In study AHE20, subject M5 could not apply the amount of ai required by the high stratum due to inclement weather. The study specifics are presented in Table 1.

Table1 Dry Flowable Scenario/Study Details

AHE17								
M1	IL/Clinton	55 gal, Airblast	165	3	20	559	173	10.7
M2	IL/Clinton	200 gal, Ground Boom	220	3	66	508	797	28.2
M3	IL/Fayette	200 gal, Slurry	3870	3	224	4,307	2,066	865
M4	IL/Fayette	200 gal, Slurry	500	5	660	8,752	15,088	179
M5	IL/Fayette	200 gal, Slurry	730	11	1,929	42,585	23,260	756
AHE18								
M1	OR/Hood River	100 gal, Tractor Mounted	375	8	15.1	220	54	17.7
M2	OR/Hood River	100 gal, Tractor Mounted	600	6	58	184	152	31.5
M3	OR/Hood River	1,400 gal, Nurse	2,000	3	193	1,664	171	10.4
M4	OR/Washington	Eductor to 300 & 500 gal tanks	6,995	24	588	8,003	2,718	393
M5	WA/Benton	300 gal, Slurry	9,129	18	1,753	3,352	1,203	163
AHE19								
M1	IL/Edwards	25 gal, Ground Boom	75	3	25.7	1,037	375	20.8

AHE17								
M2	IL/Edwards	55 gal, Airblast	145	3	71.8	1,135	670	25.5
M3	IL/Edwards	125 gal, Slurry	40	3	245	3,122	1,091	115
M4	IL/Edwards	125 gal, Slurry	350	6	712	4,112	2,056	229
M5	IL/Edwards	125 gal, Slurry	720	11	2,045	17,142	3,922	1,066
AHE20								
M1	GA/Tift	30, gal Tractor Mounted	141	6	9.9	1,184	300	180
M2	GA/Tift	320 gal, Ground Boom	1,560	5	53.4	1,163	90.4	62.8
M3	GA/Tift	300 gal, Tractor Mounted	2,400	8	179	1,807	1,419	938
M4	GA/Tift	300 & 500 gal, Tractor Mounted	5,020	15	541	23,657	2,326	895
M5	GA/Turner	400 gal, Slurry	1,390	12	1,064	47,451	16,256	4,310
AHE21								
M1	FL/Suwannee	30 gal, Tractor Mounted	145	6	5.0	98	154	24
M2	FL/Suwannee	175 gal, Tractor Mounted	525	4	50.8	369	311	10.2
M3	FL/Suwannee	1,500 gal, Tractor Mounted	6,000	4	157	854	1,857	845
M4	FL/Suwannee	200 gal, Slurry	5,260	8	495	2,244	1,477	683
M5	FL/Dixie	500 gal, Nurse	3,705	9	1,479	39,425	6,796	3,626

In field studies AHE17, AHE18, AHE20, and AHE21, a variety of Applicator MU's were also collected. These applicator MU's will be used to populate other AHETF handler scenarios. In AHE17, one Enclosed Cab Groundboom Applicator MU was collected. In AHE18, one Enclosed Cab Groundboom Applicator MU; two, Open Cab Groundboom Applicator MU's; one, Enclosed Cab Rotary Wing Applicator MU and two Enclosed Cab Fixed Wing Applicator MU's were collected. A total of 7 Groundboom Applicator MU's were collected in AHE20. All were Enclosed Cab applications with the exception of one MU which was done with an Open Cab tractor. In AHE21 two, Open Cab and two, Enclosed Cab Groundboom Applicator MU's were collected. Field study AHE19 was limited to measuring mixer/loader exposure while using dry flowable concentrate formulations.

Conclusions

The data are acceptable for use in the Dry Flowable Scenario provided that adjustments are made to the field measurements as follows:

- Adjust Face/Neck wipe values to account for the entire head (AHE17, AHE18, AHE19, AHE20, and AHE21) including area covered by respirators (if worn);
- Do not correct for field recoveries >100% (AHE17);
- Correct for potential hand rinse and face/neck wipe inefficiency (see Table 1);
- Provide breakthrough/trapping efficiency data for the OSHA Versatile Sampler (OVS) tubes (AHE17, AHE18, AHE19, AHE20 and AHE21).

Table 2 was presented at the June 2007 Human Subjects Review Board (HSRB) meeting and shows the impact on exposure estimates due to hand rinse or face/neck wipe method inefficiency.

Percent Increase in Total Exposure as a Function of Measured Exposure Contribution From Hands/Wipe Percent of Total and Residue Collection/Removal Efficiency											
Table 2		Residue Collection/Removal Efficiency (%)									
		10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
Measured Exposure Contribution (as % of Total)	10%	90%	40%	23%	15%	10%	7%	4%	3%	1%	0%
	20%	180%	80%	47%	30%	20%	13%	9%	5%	2%	0%
	30%	270%	120%	70%	45%	30%	20%	13%	8%	3%	0%
	40%	360%	160%	93%	60%	40%	27%	17%	10%	4%	0%
	50%	450%	200%	117%	75%	50%	33%	21%	13%	6%	0%
	60%	540%	240%	140%	90%	60%	40%	26%	15%	7%	0%
	70%	630%	280%	163%	105%	70%	47%	30%	18%	8%	0%
	80%	720%	320%	187%	120%	80%	53%	34%	20%	9%	0%
	90%	810%	360%	210%	135%	90%	60%	39%	23%	10%	0%
	100%	900%	400%	233%	150%	100%	67%	43%	25%	11%	0%

Note: % Increase in Total Exposure = (% Measured Exposure Contribution/% Methodology Efficiency) - % Exposure Contribution

The Agency directs the AHETF to make adjustments to the field study measurements as follows:

- If measured exposures from hands, face and neck contribute less than 20%, no action is required
- If measured exposure contribution represents between 20% and 60% of total, an automatic 50% adjustment OR submission of a validation study
- If measured exposure contribution is greater than 60%, a validation study is required

Other Observations Not Associated with the DF Scenario but Require AHETF Attention:

Wettable Powders. The AHETF has collected 5 MUs representing application of Diazinon formulated as a wettable powder (MRID 473092-05). An initial comparison suggests that the subjects (n=5) making open-cab groundboom spray applications using wettable powder formulations had different exposures than the subjects (n=29 in these and other AHETF studies that are not discussed in this review) making open-cab ground boom spray applications using liquid concentrate and dry flowable formulations. The subjects spraying suspensions of wettable powders were making ground boom applications that were spray-directed to the ground and immediately soil-incorporated. Field notes indicated that every applicator spraying the wettable powders was observed to repeatedly clear chemical from clogged filters and nozzles and clear debris from incorporation tines ranging from 5 to 14 times. The arithmetic mean exposure of the subjects using wettable powder formulations had dermal unit exposure values approximately one order of magnitude higher number than the subjects making groundboom applications using liquid and dry flowable formulations.

Table 3. Groundboom Application — Comparison of Unit Exposure Values for Open Cab (Liquid and Dry Flowable Formulation) vs. Open Cab (Wettable Powder Formulation) versus Open Cab (All Formulations)						
Statistic	Open Cab Liquid and Dry Flowable Formulation (µg/lb ai handled)		Open Cab Wettable Powder Formulation (µg/lb ai handled)		Open Cab All Formulations (µg/lb ai handled)	
	Total Dermal (n=29)	Inhalation (n=29)	Total Dermal (n=5)	Inhalation (n=4)	Total Dermal (n=34)	Inhalation (n=33)
Arithmetic Mean	10.6	0.505	112	0.806	25.5	0.541
Arithmetic Mean Standard Deviation	19.6	1.48	139	1.04	63.2	1.43
Coefficient of Variation	185	294	124	129	248	264
Geometric Mean	4.70	0.123	68.4	0.478	6.97	0.145
Geometric Mean Standard Deviation	3.27	4.06	2.58	2.58	4.44	4.16

It is possible that this finding will have an impact on future regulatory decisions involving mitigation options (e.g., use of open or enclosed cabs with chemical active ingredients that are formulated in water soluble packets). That is: will mitigating exposure for mixer/loaders by recommending the use of water soluble packets adversely impact the exposure of the applicators? This issue needs to be discussed in future meetings between the AHETF and the Agency. This formulation type appears to have a strong impact on applicator exposure and may need to be a stand alone (separate) scenario.



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Chlorothalonil

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